SCHEDULED - 3

(See Regulation 2.1.3)

FEE FOR GRANT/RENEWAL OF LICENSE

REGITRATION/ LICENSE FEE PER ANNUM IN RUPEES

1. Fees for Registration

Rs.100

2. Fees for License issued by Central

Licensing Authority:

Rs.

7500

3. Fees for License issued by State Licensing

Authority: 1. Manufacturer / Miller

Above 1 MT per day Production or 10,001 to 50,000 LPD of milk

(i) Or

Rs.

501 to 2500 MT of milk solids per annum

5000/-

(ii) Below 1 MT of Production or 501 to 10,000 LPD of milk or 2.5 MT to 500 MT

Rs.3000

/-

Of milk solids per annum

2. Hotels - 3 Star and above

Rs.

5000/-

4. All Food Service providers including restaurants/ boarding houses, clubs etc. serving food, Canteens (Schools, Colleges, Office, Institutions), Caterers, Banquet halls with food catering

Arrangements, food vendors like dabba wallas etc.

Rs.2000/

5. Any other Food Business Operator Rs.2000/-The fees paid by any applicant for a license shall not be refundable under any circumstances.

Issue of Duplicate registration or License

- (1) Where a registration certificate or license is lost, destroyed, torn, defaced or mutilated, the applicant may apply for a duplicate copy of the registration certificate or license during the validity period, accompanied with a fee amounting to 10% of the applicable License fee.
- (2) On receipt of such an application, the Licensing Authority shall grant a duplicate copy of the registration certificate or license, as the case may be to / the applicant with the word "Duplicate" appearing prominently thereon.

Mode of Payment

The payment shall be made by the Food Business Operator through online Mode of Payment.

Annexure-2

Documents to be enclosed for new application for license to State/Central Licensing Authority

- 1. Form-B duly completed and signed (in duplicate) by the proprietor/ partner or the authorised signatory
- 2. Blueprint/layout plan of the processing unit showing the dimensions in metres/square metres and operation-wise area allocation.
- 3. List of Directors with full address and contact details
- 4. Name and List of Equipments and Machinery along with the number, installed capacity and horse power used.
- 5. Photo I.D and address proof issued by Government authority of Proprietor/Partner/Director(s)/Authorised Signatory.
- 6. List of food category desired to be manufactured. (In case of manufacturers).
- 7. Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing & dispatch.
- 8. Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/ public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample
- 9. Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.)
- 10. Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm.
- 11. Copy of certificate obtained under Coop Act 1861/Multi State Coop Act 2002 in case of Cooperatives.
- 12. NOC from manufacturer in case of Re-labellers
- 13. Food Safety Management System plan or certificate if any,
- 14. Source of milk or procurement plan for milk including location of milk collection centres etc in case of Milk and Milk Products processing units.
- 15. Source of raw material for meat and meat processing plants.
- 16. Pesticide residues report of water to be used as ingredient in case of units manufacturing Packaged drinking water, packaged Mineral water and/or carbonated water from a recognised/ public health laboratory indicating the name of authorised representative of Lab who collected the sample and date of collecting sample, including source of raw water and treatment plan.
- 17. Recall plan wherever applicable, with details on whom the product is distributed.
- 18. NOCs from Municipality or local body and from State Pollution Control Board except in case of notified industrial area.

Documents to be included for renewal or transfer of license given under other existing laws

prior to these Regulations

- 1. Any change in documents or information provided during grant of previous license.
- 2. Certificate or Plan of Food Safety Management System being adopted (for units under Central Licensing it has to be a certificate from accredited agencies).
- 3. List of workers with their medical fitness certificates.
- 4. Name, qualification and details of technical personnel in charge of operation.

SCHEDULE 1

[See Regulation 2.1.2 (3)]

List of food business falling under the purview of Central Licensing Authority

- I. Dairy units including milk chilling units equipped to handle or process more than 50,000 litres of liquid milk/day or 2500 MT of milk solid per annum.
- II. Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit having installed capacity more than 2 MT per day.
- III. All slaughter houses equipped to slaughter more than 50 large animals or 150 or more small animals including sheep and goats or 1000 or more poultry birds per day.
- IV. Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum.
- V. All food processing units other than mentioned under (I) to (IV) including relabellers and repackers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units.
- VI. 100 % Export Oriented Units.
- VII. All Importers importing food items including food ingredients and additives for commercial use.
- VIII. All food business operators manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country.
- IX. Food Business Operator operating in two or more states.
- X. Food catering services in establishments and units under Central government Agencies like Railways, Air and airport, Seaport, Defence etc.

FOOD SAFETY AND STANDARDS (LICENSING AND REGISTRATION OF FOODBUSINESSES), REGULATIONS 2011

CHAPTER 1 GENERAL

- 1.1: Short title and commencement-
 - 1.1.1: These regulations may be called the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
- 1.1.2 : These regulations shall come into force on or after 5th August, 2011 1.2: Definitions-
 - 1.2.1: In these regulations unless the context otherwise requires:
 - 1. "Central Licensing Authority" means Designated Officer appointed by the Chief Executive Officer of the Food Safety and Standards Authority of India in his capacity of Food Safety Commissioner.
 - 2."District" means a revenue district in state and UTs provided that the Commissioner of Food Safety may, for the purpose of this Act declare any local area as a district on the basis of:

Concentration of specific category of food businesses which may need special attention. Risk assessment carried out by the Authority from time to time.

Any other specific regulatory requirements.

- 3. "Licensing Authority" means the Designated Officer appointed under section 36 (i) of the Act by the Commissioner of Food Safety of the state or by the Chief Executive Officer of the Food Safety and Standards Authority of India in his capacity of Food Safety Commissioner;
 - 4. "Petty Food Manufacturer" means any food manufacturer, who
 - (a) manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder; or distributes foods including in any religious or social gathering except a caterer; or(b) such other food businesses including small scale or cottage or such other industries relating to food business or tiny food businesses with an annual turnover not exceeding Rs 12 lakhs and/or whose
 - (i) production capacity of food (other than milk and milk products and meat and meat products) does not exceed $100 \, kg/ltr$ per day or

- (ii) procurement or handling and collection of milk is up to 500 litres of milk per day or
- (iii) slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.
- 5. Registering Authority" means Designated Officer/ Food Safety Officer or any official in Panchayat, Municipal Corporation or any other local body or Panchayat in an area, notified as such by the State Food Safety Commissioner for the purpose of registration as specified in these Regulations.
- 6. "State Licensing Authority" means Designated Officers appointed under Section 36(1) of the Act by the Food Safety Commissioner of a State or UT.

The expressions used in these Regulations but have not been defined herein shall have the meaning ascribed to them in the Act or as provided in the regulations, chapters and Appendices.

Chapter-2 LICENSING AND REGISTRATION OF FOOD BUSINESS

2. 1 Registration and Licensing of Food Business

All Food Business Operators in the country will be registered or licensed in accordance with the procedures laid down hereinafter;

2.1.1 Registration of Petty Food Business

- (1) Every petty Food Business Operator shall register themselves with the Registering Authority by submitting an application for registration in Form A under Schedule 2 of these Regulations along with a fee as provided in Schedule 3.
- (2) The petty food manufacturer shall follow the basic hygiene and safety requirements provided in Part I of Schedule 4 of these Regulations and provide a self attested declaration of adherence to these requirements with the application in the format provided in Annexure-1 under Schedule 2.
- (3) The Registering Authority shall consider the application and may either grant registration or reject it with reasons to be recorded in writing or issue notice for inspection, within 7 days of receipt of an application for registration.
- (4) In the event of an inspection being ordered, the registration shall be granted by the Registering Authority after being satisfied with the safety, hygiene and sanitary conditions of the premises as contained in Part I of Schedule 4 within a period of 30 days.

If registration is not granted, or denied, or inspection not ordered within 7 days as provided in above sub regulation (3) or no decision is communicated within 30 days as provided in above sub regulation (4), the petty food manufacturer may start its business, provided that it will be incumbent on the Food Business Operator to comply with any improvement suggested by the Registering Authority even later.

Provided that registration shall not be refused without giving the applicant an opportunity of being heard and for reasons to be recorded in writing.

- (5) The Registering Authority shall issue a registration certificate and a photo identity card, which shall be displayed at a prominent place at all times within the premises or vehicle or cart or any other place where the person carries on sale/manufacture of food in case of Petty Food Business.
- (6) The Registering Authority or any officer or agency specifically authorized for this purpose shall carry out food safety inspection of the registered establishments at least once in a year.

Provided that a producer of milk who is a registered member of a dairy Cooperative Society registered under Cooperative Societies Act and supplies or sells the entire milk to the Society shall be exempted from this provision for registration.

2.1.2 License for food business

(1) Subject to Regulation 2.1.1, no person shall commence any food business unless he possesses a valid license.

Provided that any person or Food Business Operator carrying on food business on the date of notification of these Regulations, under a license, registration or permission, as the case may be, under the Acts or Orders mentioned in the Second Schedule of the Act shall get their existing license converted into the license/registration under these regulations ¹[within ²[sixty months] from the date of commencement of these regulations] by making an application to the Licensing/Registering Authority after complying with the safety requirements mentioned in the Schedule 4 contained under different Parts dependent on nature of business.¹[....] In case of difficulty, the licensing authority with the approval of the Food Safety Commissioner in the State will determine the advisability of applying any specific condition keeping in view the need to ensure safety of food and public interest. No license fee will have to be paid for the remaining period of the validity of the earlier license or registration granted under any of the said Acts or Orders. Non-compliance with this provision by a Food Business Operator will attract penalty under section 55 of the Act.

Provided further that any food business operator holding Registration/License under any other Act/Order as specified under schedule 2 of the FSS Act, 2006 with no specific validity or expiry date, and otherwise entitled to obtain a license under these regulations, shall have to apply and obtain a Registration/License under these Regulations within ¹[²[sixty months] from the date of commencement of these regulations] by paying the applicable fees.

¹[Provided also that in case of difficulty, the licensing/registration authority with the approval of the Food Safety Commissioner in the State will determine the advisability of applying any specific condition keeping in view the need to ensure safety of food and public interest. Non-compliance with above provisions by a food business operator shall attract penalty as provided under section 55 of the Act.]

- (2) Notwithstanding the provisions contained in Regulation 2.1.2(1) above or in any of the registration or license certificates issued under existing Acts or Orders mentioned in the second schedule of the Act, the Licensing Authority, if it has reason to believe that the Food Business Operator has failed to comply with all or any of the conditions of the existing registration or license or the safety requirements given in Schedule 4, may give appropriate direction to the Food Business Operator to comply with.
- (3) License for commencing or carrying on food business, which falls under Schedule 1, shall be granted by the Central Licensing Authority, provided that Food Authority may through notification make such changes or modify the list given in the

Schedule I as considered necessary.

- (4) License for commencing or carrying on food business, which are not covered under Schedule 1, shall be granted by the concerned State/UT's Licensing Authority.
- (5) The Food Business Operator shall ensure that all conditions of license as provided in Annexure 3 of Form B in Schedule 2 and safety, sanitary and hygienic requirements provided in the Schedule 4 contained under different Parts depending on nature of business are complied with at all times.

Provided that the Licensing Authority shall ensure periodical food safety audit and inspection of the licensed establishments through its own or agencies authorized for this purpose by the FSSAI.

Provided further that no person shall manufacture, import, sell, stock, exhibit for distribution or sale any article of food which has been subjected to the treatment of irradiation, except under a license obtained from Department of Atomic Energy under the Atomic Energy (Control of Irradiation of Food) Regulations, 1996.

2.1.3 Application for license to the Licensing Authority

An application for the grant of a license shall be made in Form B of Schedule 2 to the concerned Licensing Authority as specified in Regulation 2.1.2 (3) and 2.1.2 (4) and it will be accompanied by a self-attested declaration in the format provided in the Annexure-1 and copies of documents mentioned in the Annexure 2 of Schedule-2 along with the applicable fees prescribed in Schedule 3.

2.1.4 Processing of Application for license

- (1) A license shall, subject to the provisions of these Regulations, be issued by the concerned Licensing Authority within a period of 60 days from the date of issue of an application ID number as provided in subsection (3) below.
- (2) If, upon scrutiny of the application within 15 days from the date of receipt of the application, the concerned Licensing Authority requires any additional information with respect to an application or if the application is incomplete, the Licensing Authority shall inform the applicant in writing, to furnish such additional information or complete the application, as the case may be, within 30 days from such notice. In case the applicant fails to furnish the required information within the stipulated time of 30 days, the application for license shall stand rejected.
- (3) On the receipt of a complete application including the additional information if asked for, the Licensing Authority shall issue an Application ID number to each applicant that will be referred to in all future correspondence between the Licensing Authority and the applicant.
- (4) After the issue of Application ID number the Licensing Authority may direct the Food Safety Officer or any other person or agency specially designated for such functions to inspect the premises in the manner prescribed by the Food Safety and Standard Authority of India in accordance with these Regulations. Such Inspecting Officer or person may issue a notice to the applicant, if it deems fit, guiding food business operator

on necessary steps to be taken or changes or alteration to be made in the premises in order to ensure general sanitary and hygienic conditions as specified in Schedule 4. The applicant shall carry out the required steps, changes or alterations and intimate the Licensing Authority within 30 days or such period as may be allowed by the Licensing Authority.

(5) Within a period of 30 days from receipt of an inspection report excluding the time taken by the applicant in complying with the advice, if any, given in the inspection report and verification thereof, the concerned Licensing Authority shall consider the application and may either grant license or reject the application.

Provided that before refusing license an applicant shall be given an opportunity of being heard and the reasons for refusal shall be recorded in writing.

(6) The Licensing Authority shall issue a License in Format C under Schedule 2 of these Regulations, a true copy of which shall be displayed at a prominent place at all times within the premises where the Food Business Operator carries on the food business.

2.1.5 Procedure for License in certain local areas

- (1) A single license may be issued by the Licensing Authority for one or more articles of food and also for different establishments or premises in the same local area including collection and chilling units run by milk cooperatives or its members.
- (2) The Chief Executive Officer of the Food Safety and Standards Authority of India in the capacity of Food Safety Commissioner may appoint a Designated Officer or Food Safety Officer for Central Government organizations like Railways, Defense etc., which have a large number of food establishments, to ensure food safety in those establishments and to ensure that all other conditions laid down for running food business under the Act and these Regulations are complied with. Provided further that the Food Authority may carry out food safety audit of these establishments once in a year through its own or accredited agencies.

2.1.6 Commencement of Business

An applicant may commence his food business and the concerned licensing Authority shall not deny the applicant to commence such business if, from the date of making the completed application, a license is not issued within 60 days or the applicant has not received any intimation of inadequacy under Regulation 2.1.4(2) or inspection report indicating defects from the concerned Licensing Authority under Regulation 2.1.4(4)

2.1.7 Validity and Renewal of Registration and License

- (1) A Registration or license granted under these Regulations shall be valid and subsisting, unless otherwise specified, for a period of 1 to 5 years as chosen by the Food Business Operator, from the date of issue of registration or license subject to remittance of fee applicable for the period and compliance with all conditions of license.
- (2) Any application for the renewal of a registration or license granted under these Regulations shall be made in Form A or B of Schedule 2, as the case may be, not later than 30 days prior to the expiry date indicated in the license.

- (3) The Registration or License shall continue to be in force till such time that the orders are passed on the renewal application which in no case shall be beyond 30 days from the date of expiry of registration or license.
- (4) Any renewal application filed beyond the period mentioned under Regulation 2.1.7 (2) above but before the expiry date, shall be accompanied by a late fee of Rs 100 per day for each day of delay.

¹[Provided that in case of registration, late fee of Rs. 100 per day for each day of delay shall not be applicable]

- (5) Any Registration or license for which renewal has not been applied for within the period mentioned in Regulation 2.1.7 (2) or 2.1.7 (4) above shall expire and the Food Business Operator shall stop all business activity at the premises. The Food Business Operator will have to apply for fresh Registration or license as provided in Regulation 2.1.1 and 2.1.3 as the case may be, if it wants to restart the business.
- (6) Food Business Operator having valid certificate of an accredited food safety auditor or from an agency accredited by Food Authority or any other organisation notified by food Authority for this purpose will not be normally required to be inspected before renewal of license.

Provided that Designated Officer may order an inspection before renewal if considered necessary for reasons to be recorded in writing.

- 2.1.8 Suspension or cancellation of Registration Certificate or license
- (1) The Registering or Licensing Authority in accordance with the provisions of section 32 of the Act may, after giving the concerned Food Business Operator a reasonable opportunity of being heard, suspend any registration or license in respect of all or any of the activities for which the registration/license has been granted under these Regulations after recording a brief statement of the reasons for such suspension, if there is reason to believe that the Food Business Operator has failed to comply with the conditions within the period mentioned in any Improvement Notice served under Section 32 of the Act. A copy of such statement shall be furnished to the concerned Food Business Operator whose Registration or license has been suspended.
- (2) The registering or Licensing Authority, as the case may be, may direct an inspection of the Food Business Operator's premise(s) within a reasonable period which shall not be less than 14 days from the date of order of suspension.
- (3) In the event that the Registering or Licensing Authority is of the opinion, on a review of the inspection report, that the Food Business Operator has still failed to rectify the defects or omissions or comply with the conditions of the improvement notice causing the suspension, such authority may cancel the license/registration of the Food Business Operator after giving him an opportunity to show cause as provided under Section 32 (3) of the Act.
- (4) Notwithstanding anything contained in these Regulations, the Registering or Licensing Authority may suspend or cancel any registration or license forthwith in the interest of public health for reasons to be recorded in writing.

- (5) A suspension or cancellation of registration or license under these Regulations shall not entitle the Food Business Operator for any compensation or refund of fee(s) paid in respect of the registration certificate or license or renewal thereof.
- (6) After a period of 3 months from the date of cancellation under Regulation 2.1.8 (3) above the Food Business Operator may make fresh application for Registration or license to the concerned authority if all observations made in the improvement notice have been complied with.
- 2.1.9 Modifications, Expansion or Changes in premise(s) after grant of license or registration
- (1) Food Business Operators shall ensure that the Registering or Licensing Authority always has up-to-date information on their food business establishments and shall inform the relevant Authority of any modifications or additions or changes in product category, layout, expansion, closure, or any other material information based on which the license was granted and such information shall be conveyed before the changes occur.

Provided that any change that alters the information contained in the license certificate shall require an approval or endorsement in license prior to start of business with such changes. The Food Business Operator shall submit the original license to the Licensing Authority along with a fee equivalent to one year license fee for effecting necessary changes. The licensing Authority may approve and issue an amended license incorporating such changes in activities within 30 days from the date of receipt of such information. While approving the afore mentioned changes the concerned registering or Licensing Authority shall take into account the feasibility of carrying on the business and the legal and other relevant aspects of the desired modifications or additions or changes in activities and, if required, may order an inspection of the premises before granting the approval.

2.1.10 Mode of payment:

All fees and charges payable under these regulations shall be paid vide pay order or demand draft or any online mode of payment as may be prescribed in this regard, by the concerned Food Safety Commissioner.

- 2.1.11 Transfer of registration certificate or License in case of death
- (1) In the event of death of the holder of a Registration certificate or license, such certificate or license shall subsist for the benefit of the legal representative or any family member of the deceased or until the expiry of:—
 - (a) the period of 90 days from the date of death of the holder of a Registration certificate or license; or (b) such longer period as the Designated Officer may allow, for reasons to be recorded in writing.
 - (2) The legal representative or family member of the deceased holder of the registration certificate or license shall apply to the concerned Authority for transfer of such certificate or license in his favour.

- (3) The registering or Licensing Authority, as the case may be, may, after making such enquiry as it may deem fit, either approve the transfer of the Registration certificate or license if satisfied that the applicant is the legal representative, or refuse the request. Provided that the registering or licensing authority shall not refuse the request without giving the applicant an opportunity of being heard and for reasons to be recorded in writing.
- (4) Upon filing of application for transfer and pending the decision of the authority, the registration or license shall continue to be in force.

2.1.12 Appeal

(1) A Food Business Operator aggrieved by an order of the Registering Authority or Licensing Authority, as the case may be, under these Regulations may prefer an appeal to the concerned Designated Officer or the Food Safety Commissioner, as per provisions laid down under Section 31(8) and 32 (4) - (5) of the Act.

2.1.13 Return

(1) Every ¹[manufacturer and importer who has been issued a license] shall on or before 31st May of each year, submit a return electronically or in physical form as may be prescribed by the concerned Food Safety Commissioner, in 'Form D-1' provided in Schedule 2 of these Regulations to the Licensing Authority in respect of each class of food products handled by him during the previous financial year.

Provided however that every licensee engaged in manufacturing of milk and/or milk products shall file half yearly returns for the periods 1st April to 30th September and 1st October to 31st March of every financial year in the form D-2, as provided in Schedule-2 of these regulations. Such returns will be filed within a month from the end of the period.

- (2) A separate return shall be filed for every license issued under the Regulations, irrespective of whether the same Food Business Operator holds more than one license.
 - (3) Any delay in filing return beyond 31st May of each year shall attract a penalty of Rs 100 per day of delay.

2.1.14 Food Business Operator to be bound by directions or order

- (1) Every Food Business Operator to whom any direction or order is issued in pursuance of any provisions of this regulation shall be bound to comply with such directions or regulation and any failure on the part of the Food Business Operator to comply with such direction or order shall be deemed to be contravention of the provisions of these Regulations and will attract legal action under the provisions of the Act.
- (2) Guarantee Every manufacturer, distributor or dealer selling an article of food to a vendor shall give either separately or in the bill, cash memo, or label a warranty in Form E. (*Refer Form A for form of Guarantee*)

2.1.15 Power of State/UT governments to constitute advisory committee

The state/UT Governments, may, if required designate an existing advisory committee at panchayat/district/ state level or where such a committee does not exist, constitute an advisory committee to assist, aid or advise on any matter concerning food safety.

2.1.16: Jurisdiction of Designated officer

The Commissioner of Food Safety shall, by an order, appoint the Designated officer, who shall not be below the rank of a Sub- Divisional Officer, to be in-charge of food safety administration for each district as defined under regulation 1.2.1 (2)

SCHEDULE 1

[See Regulation 2.1.2 (3)]

List of food business falling under the purview of Central Licensing Authority

- I. Dairy units including milk chilling units equipped to handle or process more than 50,000 litres of liquid milk/day or 2500 MT of milk solid per annum.
- II. Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit having installed capacity more than 2 MT per day.
- III. All slaughter houses equipped to slaughter more than 50 large animals or 150 or more small animals including sheep and goats or 1000 or more poultry birds per day.
- IV. Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum.
- V. All food processing units other than mentioned under (I) to (IV) including relabellers and repackers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units.
- VI. 100 % Export Oriented Units.
- VII. All Importers importing food items including food ingredients and additives for commercial use.
- VIII. All food business operators manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country.
- IX. Food Business Operator operating in two or more states.
- X. Food catering services in establishments and units under Central government Agencies like Railways, Air and airport, Seaport, Defence etc.